

REMARKS

Claims 39-40, 42, 45, 47, 49-70, 72, 74-83, and 85 are currently pending in the present application. All claims are rejected.

In view of the remarks set forth below, further and favorable consideration is respectfully requested.

1. Claim Construction of the Phrase “Consisting Of”

The Official Action states at page 3 that Applicant's prior arguments regarding the 35 U.S.C. 103(a) rejections for claims 39, 40, 42, 45, 47, 49-70 and 74-83 were found not persuasive and thus upheld. The Official Action then states the following at page 3:

The transitional phrase "consisting essentially of" limits the scope of a claim to the specified materials or steps "and those that do not materially affect the basic and novel characteristic(s)" of the claimed invention *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976). For the purposes of searching for and applying prior art under 35 U.S.C. 102 and 103 , absent a clear indication in the specification or claims of what the basic and novel characteristics actually are, "consisting essentially of" will be construed as equivalent to "comprising." See, *PPG*, 156 F.3d at 1355,48 USPQ2d at 1355. If an applicant contends that additional steps of materials in the prior art are excluded by the recitation of "consisting essentially of," applicant has the burden of showing that the introduction of additional steps or components would materially change the characteristics of applicant's invention *In re De Lajarte*, 337 F.2d 870, 143 USPQ 256 (CCPA 1964).

Importantly, Applicants make clear that the present claims do not recite “consisting essentially of” language. The present claims clearly only recite “consisting of” language in regard to the components of the recited composition. Accordingly, the law concerning the interpretation of “consisting essentially of” is irrelevant in regard to the present claims. See MPEP 2111.03 regarding transitional phrases. Accordingly, Applicants do not have the burden of showing that the introduction of additional steps or components would materially change the characteristics of these claims.

2. Rejection of Claims 39, 40, 42, 45, 47, 49-62, 64, 66-70, 74, 75, 77-80, 83 and 85

Under 35 U.S.C. §103(a)

The Official Action states that claims 39, 40, 42, 45, 47, 49-62, 64, 66-70, 74, 75, 77-80, 83 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. (U.S. Patent No. 5,993,787) in view of Shelton (U.S. Patent No. 4,083,956).

Regarding Sun, the Official Action alleges at page 8 that Sun et al. teaches “anhydrous topical preparations with allegedly good physical stability and excellent cosmetic attributes comprising propylene carbonate; one or more short chain alcohols and/or glycols, such as ethanol, isopropanol, propylene glycol, polyethylene glycol, etc; glycerol (glycerine); and an active ingredient (see Abstract, in particular.) The topical preparations are formulated as, e.g. gels (see column 3, lines 14-19, in particular.) Active ingredients are selected from antifungal agents, such as miconazole nitrate, ketoconazole, etc. (see column 6, lines 1-12, in particular.)”

Regarding Shelton, the Official Action then alleges at page 8 (emphasis added) “For clarification, the Examiner has cited Shelton to teach that *propylene carbonate is a gel promoting agent* that generally comprise from about 1.0% to 3.0% by weight of the composition (see column 4, lines 2-8).”

The Examiner then concludes “it would have been obvious to one of ordinary skill in the art to optimize the concentrations of said components to arrive at the concentrations as herein envisioned.”

RESPONSE

Applicants respectfully traverse this rejection. The combination of cited references does not teach or suggest Applicants' claimed subject matter as a whole as recited in the claims. Applicants assert that the cited references fail to establish a *prima facie* case of obviousness against the presently pending claims.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court held in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR*, 550 U.S. 398 at 417.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

The Combination of References Does Not Teach or Suggest All Claimed Features

The presently pending claims, as exemplified by present claim 39, relate to an anhydrous composition formulated for topical delivery *consisting of*: (a) an anhydrous vehicle consisting of about 1 to about 50 percent by weight of ethanol, (b) a penetration enhancer consisting of about 1 to about 50 percent by weight of propylene glycol, (c) a humectant consisting of polyethylene glycol and glycerin, in a combined amount of about 10 to about 80 percent by weight, (d) ketoconazole in an amount of about 0.5 to about 3 percent by weight, (e) *a gelling agent*, and (f) optionally one or more components selected from the group consisting of emollients, chelating agents, pH adjusters, antioxidants, viscosifiers, colorants, fragrances, UV stabilizers, and sunscreens, and wherein the composition is formulated as an anhydrous gel.

Sun et al. discloses propylene carbonate, but makes no reference to the propylene carbonate being a "gelling agent." Shelton is cited for allegedly teaching that *propylene carbonate is a gel promoting agent* that generally comprises from about 1.0% to 3.0% by weight of the composition (at column 4, lines 2-8).

Importantly, Applicants submit that propylene carbonate is not a gelling agent. Propylene carbonate is defined as a "viscosity decreasing agent" in the International Cosmetic Ingredient Dictionary and Handbook (7th Edition), convenience copy attached. Propylene carbonate is a polar solvent.

The example the Examiner has identified in Shelton is a case where propylene carbonate activates a Bentone® clay in an antiperspirant composition, where the clay then becomes a gelling agent. This is clearly supported by the attached supplier information which describes that Bentone® clays are rheological modifying agents, which require *activation* with a polar solvent such as acetone, ethanol, methanol or *propylene carbonate*.

This example in Shelton is unique to certain clays and is not necessarily true of all clays or all uses of propylene carbonate-clay compositions.

Thus, it is not true to say that propylene carbonate is a gelling agent, let alone that Shelton teaches the use of propylene carbonate as a gelling agent. Accordingly, *Applicants submit that one of ordinary skill in the art would understand that "propylene carbonate" can be described as a "gelling activator" in the narrow context of certain clays, and would nevertheless understand that it is most certainly not a "gelling agent" as presently claimed.*

Furthermore, Sun et al. requires the presence of propylene carbonate "as the primary solvent for the active ingredients because of its considerable solubilization properties." Col. 5, lines 24-45. Accordingly, all of the products formulated by Sun et al. contain approximately 20 wt % propylene carbonate, which would be an appropriate solvent amount. In contrast, Shelton has been cited by the Examiner "to teach that propylene carbonate is a gel promoting agent that generally comprise from about 1.0% to 3.0% by weight of the composition". While propylene carbonate could potentially be used as a viscosity decreasing agent per Shelton, it clearly cannot operate as a viscosity increasing agent, as alleged by the Examiner, based on the teachings of Shelton when used in the amounts required by Sun et al.

Accordingly, since propylene carbonate is not a gelling agent the combination of cited references does not teach all of the recited features in the claims as required by *In re Wilson*.

For at least this reason, the Examiner has not met the burden for showing a *prima facie* case of obviousness. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

3. Rejection of Claims 63 and 65 under 35 U.S.C. §103(a)

Claims 63 and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. in view of Shelton, as applied to claims 39, 40, 42, 45, 47, 49-62, 64, 66-70, 74, 75, 77-80, 83 and 85 above, in further view of U.S. Patent No. 5,208,257 to Kabara.

Kabara is cited for teaching a topical antimicrobial composition, and that chelating agents, such as citric acid, are useful (see column 7, lines 64 through column 8, line 7, in particular.)

Applicants traverse the rejection, and incorporate herein by reference the arguments made above in regard to the combination of Sun et al. and Shelton. The combination of references with Kabara does not correct the deficiencies noted above for the combination of Sun and Shelton. Kabara does not teach or suggest that propylene carbonate is a gelling agent.

Accordingly, since propylene carbonate is not a gelling agent the combination of cited references does not teach all of the recited features in the claims as required by *In re Wilson*.

For at least this reason, the Examiner has not met the burden for showing a *prima facie* case of obviousness. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

4. Rejection of Claims 76 and 81-82 under 35 U.S.C. §103(a)

Claims 76 and 81-82 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sun et al. in view of Shelton as applied to claims 39, 40, 42, 45, 47, 49-62, 64, 66-70, 74, 75, 77-80, 83 and 85 above, in further view of Thornfeldt (U.S. 5,231,087).

Thornfeldt is cited for teaching a method of treating seborrheic dermatitis.

Applicants traverse the rejection, and incorporate herein by reference the arguments made above in regard to the combination of Sun et al. and Shelton. The combination of references with Thornfeldt does not correct the deficiencies noted above for the combination of Sun and Shelton. Thornfeldt does not teach or suggest that propylene carbonate is a gelling agent.

Accordingly, since propylene carbonate is not a gelling agent the combination of cited references does not teach all of the recited features in the claims as required by *In re Wilson*.

For at least this reason, the Examiner has not met the burden for showing a *prima facie* case of obviousness. Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection.

5. Double Patenting Rejections

Claims 39-40, 42, 45, 49, 53-54, 58, 62-63, 65, 69, 72, and 74-83 are rejected on the grounds of nonstatutory obviousness-type double patenting over US Patent No. 7,179,475. Applicants note that claims 47, 50-52, 55-57, 59-61, 64, 66-68, 70, and 85 were not included in this rejection.

Applicants request that these rejections be held in abeyance until allowable subject matter is indicated in light of the arguments and amendments presented herein.

CONCLUSION

In view of the foregoing, Applicants submit that the application is in condition for immediate allowance. Early notice to that effect is earnestly solicited. The Examiner is invited to contact the undersigned attorney if it is believed that such contact will expedite the prosecution of the application.

If a fee is required for an extension of time under 37 C.F.R. §1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account No. 14-0112.

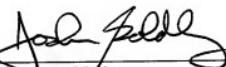
Respectfully submitted,

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